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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,597	10/09/2001	Todd M. Boyce	285-118 DIV	8157

7590 10/10/2003

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EXAMINER

YAO, SAMCHUAN CUA

ART UNIT PAPER NUMBER

1733

DATE MAILED: 10/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N . 09/973,597	Applicant(s) BOYCE ET AL.	
	Examiner Sam Chuan C. Yao	Art Unit 1733	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

### Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-32 and 36-40 is/are pending in the application.
- 4a) Of the above claim(s) 36-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 14-32, drawn to a method of forming an osteogenic osteoimplant, classified in class 156, subclass 296.
  - II. Claims 36-40, drawn to an osteoimplant, classified in class 623, subclass 23.61.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as depositing a biological-binder impregnated mass of bone particles having a paste or gel-like consistency; and then heating the mass of bone particles to activate and harden the binder.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Mr. Peter Dilworth on 09-30-03 a provisional election was made with traverse to prosecute the invention of Group I, claims 14-32. Affirmation of this election must be made by applicant in replying to this

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Office action. Claims 36-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 22-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22-23 are indefinite, because the limitation "*lateral force*" is not understood. Does this limitation require applying a tensional force? If not, when a "*compressive*" force is applied throughout the surface area of a mass of elongated bone particles, shouldn't a lateral force inherently be applied on the mass of particles?

***Claim Rejections - 35 USC § 102/103***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 14-32 are rejected under 35 U.S.C. 102(a,e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 99/39757 A1. See the whole disclosure.

It is acknowledge that, WO '757 does not explicitly teach the recited porosity or void volume of a resultant osteoimplant. However, in light of the similarity of the production processes between WO '757 and the present invention, it would be reasonably to expect that, a resultant osteoimplant of WO '757 must inherently have a substantially identical, if not the same, characteristics as a resultant osteoimplant of the presently recited claims. In any event, absent any showing of unexpected result, forming an osteoimplant which has the recited porosity is taken to be well within the purview of choice in the art. For instance, WO '560 "*partially or complately*" filling pores of a resultant osteoimplant with "one or more medically/surgically useful substances which promote or accelerate new bone growth or bone healing ..." (page 11 lines 1-8). This process would clearly significantly reduce the pore volume in a resultant osteoimplant.

Note: Where ... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the

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PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. **Whether the rejection is based on “inherency” under 35 USC § 102, on prima facie obviousness” under 35 USC § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO’s inability to manufacture products or to obtain and compare prior art products.”** In re Best, 562 F2d 1252, 1255, 195 USPQ 430, 433-4 (CCPA 1977).

11. Claims 14-32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dowd et al (US 5,507,813).

With respect to claims 14, 21 and 31, Dowd et al discloses a process of making a surgically implantable shaped article from a mass of elongated bone particles, the process comprises depositing “*slurried*” mass of elongated bone particles into a forming means such as a “*flat sheet, mesh screen or three-dimensional mold*”; and, compressing the mass of elongated bone particles in the forming means to form the implantable shaped article (col. 4 line 58 to col. 5 line 26).

As for a recited limitation of forming an implantable shaped article “*having not greater than about 32% void volume*”(emphasis added), an upper-bound of “*about 32% void volume*” is taken to read on a lower-bound void volume of “*about 37%*”. Note: in Applicant’s specification, it was indicated that the implantable shaped article has void volume of “*about 37%*” (emphasis added; Pre-Pub 2002/0035401 A1, paragraph 0022). In any event, it would have been obvious in the art to form an implantable shaped article having “*about 32% void volume*”, because the prior art range is close enough that one skilled in the art would have reasonably expected it to have the same desired result/properties.

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All that would have been required to form an osteoimplant having the recited porosity would have simply been to perform any one or combinations of the following process steps:

saturating a mass of bone particles with a biocompatible binder so that, the binder substantially permeates into pores of the mass of elongated bone particles;

forming a more dense osteoimplant by subjecting a mass of elongated bone particles to a higher compressive force; and

filling the pores with biocompatible powdered fillers and/or medically/surgically useful substances.

It is interesting to note that, Down et al expressly teach "*varying compression force*" to form an implantable "*which is more pliable or less pliable*" (col. 6 lines 46-48).

With respect to claim 15, see claim 3 of the Dowd et al patent.

With respect to claims 16, see column 3 line 66 to column 4 line 13.

With respect to claim 17 and 19-20, see column 5 lines 12-26.

With respect to claim 24, it is conventional in the art to apply non-stick coating onto pressing surfaces of various forming molds so that, a molded article does not stick onto the pressing surfaces.

With respect to claim 25, the limitation in this claim is taken to be conventional in the art in order to prepare a dried mass of particles for molding.

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With respect to claims 26-27, the limitations in these claims are conventional or old in the art.

With respect to claims 18, 28-30 and 32, applying a cross-linking agent or thermosetting agent to bond a mass of particles is conventional in the art. It is also a common practice in the art to prevent an in-growth of soft tissue to a certain section of an implantable shaped article. One expeditious way to accomplish this is to form a sectional/localized cross-linked bonding of bone particles. See for example WO 99/39757 cited in numbered paragraph 8 above and also see WO 00/35510 for occluding a portion of a surface area of a coherent mass of bone particles.

### ***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Meredith (US 2003/0036800 A1) is cited as a reference of interest showing a composite bone implant having a porosity volume of ranging from 5-50% (claims 53-55).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sam Chuan C. Yao whose telephone number is (703) 308-4788. The examiner can normally be reached on Monday-Friday with second Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael W Ball can be reached on (703) 308-2058. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0651.



Sam Chuan C. Yao  
Primary Examiner  
Art Unit 1733

Scy  
09-30-03